

Exhibit 38

Insulin prices have skyrocketed, putting drug makers on the defensive



By [Ed Silverman](#)¹ April 5, 2016



According to a new analysis, some people cannot afford the cost of insulin, which has risen sharply. *Jean-Francois Monier/AFP/Getty Images*

Here's a sticking point for diabetics: the cost of insulin more than tripled — from \$231 to \$736 a year per patient — between 2002 and 2013, according to a new [analysis](#)³.

The increase reflected rising prices for a milliliter of insulin, which climbed 197 percent from \$4.34 per to \$12.92 during the same period. Meanwhile, the amount of money spent by each patient on other diabetes medications fell 16 percent, to \$502 from \$600, according to a research letter published Tuesday in the Journal of the American Medical Association.

“Insulin is a life-saving medication,” said Dr. William Herman, a coauthor of the analysis and a professor of medicine and epidemiology at the University of Michigan School of Public Health. “There are people with type 1 diabetes who will die without insulin. And while there have been incremental benefits in insulin products, prices have been rising. So there are people who can't afford them. It's a real problem.”

The analysis also found that the cost of various widely used oral diabetes drugs either dropped in price or did not rise nearly as significantly as insulin. Metformin, for instance, which is available as a generic, fell to 31 cents in 2013 from \$1.24 per tablet in 2002. And the newer class of diabetes drugs known as DPP-4 inhibitors rose 34 percent since becoming available in 2006.

The researchers analyzed data from nearly 28,000 diabetes patients found in the Medical Expenditure Panel, a database on health care costs maintained by the US Department of Health and Human Services. About 1 in 4 people used insulin and two-thirds took a pill. Toward the end of the study period, a small percentage began taking new injectable medicines that are designed to complement pills.

There have been previous efforts to track insulin prices in recent years, but the researchers explained this is the first attempt to examine national pricing data in this way for an extended period of time. And the findings are likely to further fuel the hot-button national debate over the rising cost of prescription medicines, which has also become a talking point in the presidential campaign.

More than 29 million Americans, or 9.3 percent of the population, have some form of diabetes, according to the US Centers for Disease Control and Prevention. Not surprisingly, there are numerous companies competing to grab a share of the market and newer forms of insulin have been introduced, notably, analog insulins that are man-made and differ slightly from human insulin.

Payers report that unit costs are rising. One exception has been the widely used long-acting form of insulin called Lantus, which is marketed by Sanofi. The drug maker has been encountering pushback from insurers, and so the unit cost for the medicine fell nearly 14 percent last year, according to Express Scripts, the nation's largest pharmacy benefits manager.

More competition is expected for Lantus later this year when Eli Lilly is expected to launch a biosimilar version of the medication. But to what extent this drug will be affordable remains to be seen. Typically, when a generic version of a pill becomes available, the price drops 80 percent or more. But biosimilars are new to the United States and are forecast to cost about 20 percent to 30 percent less than a brand-name drug.

Meanwhile, some doctors say diabetic patients, who are typically 60 years old or more, have difficulty paying for drugs, especially those who have trouble once they hit the donut hole in the Medicare Part D program and have to cover costs themselves. "The cost of therapy is huge," said Dr.

Jane Bridges, a diabetologist in Vincennes, Ind. “I have patients who tell me that they have to stretch out the use of their medicines.”

But the Pharmaceutical Research and Manufacturers of America argued that focusing on list prices “misrepresents” reality. The industry trade group maintained that wholesale prices generally do not correspond to net prices — what companies, unions, and government agencies pay — because drug makers offer rebates. The group cited an analysis by SSR Health that net prices declined last year.

Spokespeople for Eli Lilly and Novo Nordisk, two of the largest manufacturers of diabetes medicines, echoed that argument and both companies noted that patient-assistance programs are available. The Novo spokesman added that “making comparisons between insulin and oral medications are not appropriate as each medication is designed to support a patient’s specific glucose-control needs.”

A Lilly spokeswoman maintained that the net price for its Humalog insulin rose an average of 1.6 percent annually from 2010 to 2015. However, she did not respond to questions about the rebates that were offered. Drug makers and pharmacy benefits managers are facing increasing criticism for their failure to disclose rebates and discounts.

One analyst, meanwhile, contended that rising prices may not have any impact on patient outcomes.

“I don’t think you can draw a straight line from the rising cost of insulin to outcomes,” said David Kliff, who publishes Diabetic Investor. “Very few patients pay out of pocket for cost of insulin. So I don’t think prices truly impact the patient pocket book. There’s only a small percentage who don’t have insurance or enough insurance.”

But another author of the analysis disagreed.

“High costs can lead to reduced compliance, but more importantly the cost-effectiveness of high cost therapies ... should be assessed, so they produce a greater clinical benefit for the patient,” Philip Clarke, a professor of health economics at the University of Melbourne in Australia. Other countries, he noted, routinely assess cost-effectiveness when setting prices for government-subsidized drugs.

About the Author



Ed Silverman¹

Pharmalot Columnist, Senior Writer

Ed Silverman, a senior writer and Pharmalot columnist at STAT, has been covering the pharmaceutical industry for nearly three decades.

ed.silverman@statnews.com⁷

[@Pharmalot](#)⁸

[linkedin.com/in/edsilverman/](https://www.linkedin.com/in/edsilverman/)⁹

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